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**UNITED STATES DEPARTMENT OF COMMERCE
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08/452,227 05/26/95 BLATT

G 16683-1

EXAMINER

SHAY, R

33M1/0509

ART UNIT

PAPER NUMBER

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3308

DATE MAILED:

05/09/96

 This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

 A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133
Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input checked="" type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. ^{substitute} |
| 3. <input checked="" type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

- 1.
- ☒
- Claims
- 1-24
- are pending in the application.

 Of the above, claims 11-20 are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.
3. ☒ Claims 8-10 are allowed.
4. ☒ Claims 1-3, 5-7 and 21-24 are rejected.
5. ☒ Claims 4 are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

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- ✓ 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-10 and 21-24, drawn to a method for treating a joint, classified in Class 623, subclass 18.

Group II. Claims 11-20, drawn to an implant or joint treating kit, classified in Class 623, subclass 16.

The inventions are distinct, each from the other because of the following reasons:

- ✓ 2. Inventions II and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as implantation at a site within the body which does not have a mating joint surface.
- ✓ 3. Because these inventions are distinct for the reasons given above and the search required for Group I is not coextensive with the search required for Group II, restriction for examination purposes as indicated is proper.
- ✓ 4. During a telephone conversation with James Hann on December 28, 1995 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-10 and 21-24. Affirmation of this election must be made by applicant in responding to this Office action.

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Claims 11-20 are withdrawn from further consideration by the Examiner, 37 C.F.R.

§ 1.142(b), as being drawn to a non-elected invention.

5. Claims 6 and 21-24 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

✓ In claim 6, lines 2-3 "said complementary surface shapes" lacks antecedent basis. It appears that this claim was intended to depend from claim 5, rather than claim 3.

✓ In claim 21, on line 2 "the surface" lacks antecedent basis and should be changed to "the at least one surface", with "being one of" (also on line 2) changed to "being one or more of" for this phrase to make sense.

For 21, 22
See marked
text on
and p. 5

✓ Claims 21, 22 and 24 are indefinite and appear to be incomplete. It is unclear, based on the disclosure, how the claimed maintaining step could be performed without the insert being bioresorbable. If a permanent, non-bioresorbable implant is used to maintain the spacing, how will any fibrocartilage which forms on the surface covered by the implant form the surface along which the relative movement occurs, as required by the last two lines of claim 21? It appears the movement would occur along the surface formed by the implant.

✓ Claim 24 is indefinite because it does not set forth enough structure in the step to support the function on line 10 of that claim. For the resorption referred to on line 10 to occur, then line 5 should be changed from "placing an implant" to "placing a bioresorbable implant". Additionally, "gradually resorbing" is not a step that is actively performed, which is

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how line 10 is phrased. It is something that you permit the body to do. The claim should be reworded to reflect this.

✓ 6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

modification
7. Claims 1, 5⁽⁷⁾ and 21-24 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Stone et al. (5,306,311).

drop
8. Claims 21-22 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by McDowell (5,108,441).

9. Claims 21-22 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by

Dow Corning Wright Silastic Trapezial Implant H.P. Brochure.

10. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

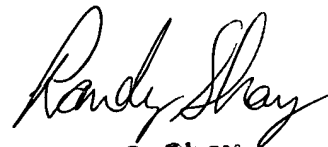
Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

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11. Claims 2-3 are rejected under 35 U.S.C. § 103 as being unpatentable over Stone et al. (5,306,311) in view of Delcommune et al. (5,007,939).

Stone et al. disclose all steps claimed except for selecting the claimed material for the bioresorbable implant. As taught by Delcommune et al., the claimed material is old and well known for use in bioresorbable implants, making selection of this known material for this known person obvious to one of ordinary skill in the art.

- ✓ 12. Claim 4 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
- ✓ 13. Claims 8-10 are allowable over the prior art of record.
- ✓ 14. Any inquiry concerning this communication should be directed to Randy Shay at telephone number (703) 308-2907 on Mondays and Thursdays.


Randy C. Shay
Primary Examiner
Art Unit 3308

R. Shay

April 25, 1996